K112188

Section 05 – 510(k) Summary (SMDA Requirements)

FEB - 3 2012

This Summary of Safety And Effectiveness is submitted in accordance with 21 CFR 807.92.c.

1 – Administrative Information

1- a. Date Prepared: July 12, 2011

1-b. 510(k) Submitter:

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1- e. Establishment registration number: 8044015

ISO 13485

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2 – Device Information

2-a. Common Name of device:	Bone Cutting Material and Accessories
2-b. Trade Name of device:	PIEZOTOME SOLO PIEZOTOME SOLO LED (available in option)
2-c. Classification regulation:	21 CFR 872.4120
2-e. Medical Device Class:	II
2-f. Panel:	Dental
2-g. Product code:	DZI

3 – Identification of legally marketed device(s)

The Substantial Equivalence (SE) of the Device is based on the Predicate Device identified in the Table 01.

Table 01 – Identification of legally marketed device

Trade Name	Manufacturer	Product Code	510(k) number	Date Cleared
IMPLANT CENTER 2	SATELEC	DZI	K091252	July 22, 2009

4 – Description of the Device

The New Device is a dental operative unit that supplies utilities to and serves as a base for Satelec Bone Cutting Handpiece (K091252, cleared July 22, 2009).

The New Device uses Piezoelectric Ultrasound Technology to generate mechanical micro vibrations for bone cutting, with minimal trauma to soft tissue.

The device is supplied with Dental Bone Surgery Tips for use in dental surgery, including osteotomy, osteoplasty and implantology. Also, the New Device uses accessories such as Piezoelectric Handpiece, Multifunction Footswitch, Bracket and Irrigation Tubing.

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5 – Intended Use

The intended use of the Satelec PIEZOTOME SOLO (or PIEZOTOME SOLO LED available in option) is to supply utilities to and serve as a base for dental tools and accessories for use by qualified dental practitioners.

6- Technological characteristics of the Device compared to the Predicate Device

Technological characteristics of the Device are the same as the Predicate Device.

Technological perspective:
The Device and the Predicate Device use the same technology (piezoelectricity technology).

Material perspective:
The Device and the Predicate Device are very similar because the casings are made in self-extinguishing material (UL94-V0).

Design perspective:
The Device and the Predicate Device use the same:

- Switching Power Supply.
- Motherboard.
- Irrigation Board.
- Light Board.
- Irrigation Tubing.
- Piezoelectric Handpiece.
- Dental Bone Surgery Tips.
- Bracket.

Also, both devices are equipped with a large display and a Multifunction Footswitch.

Energy source perspective:
The Device and the Predicate Device:

- Use the same input energy source (electric power supply).
- Deliver the same output energy source (ultrasonic micro-vibration).

Material in contact with the patient:
Because of the Device and the Predicate Device use the same Irrigation Tubing, Piezoelectric Handpiece and Dental Bone Surgery Tips, the materials in contact with the patient are exactly the same.

7 - Determination of substantial equivalence

The Satelec PIEZOTOME SOLO (or PIEZOTOME SOLO LED available in option) is a dental operative unit that supplies utilities to and serves as a base for Satelec Bone Cutting Handpiece. The Satelec PIEZOTOME SOLO (or PIEZOTOME SOLO LED available in option) Indications for Use are similar to the Satelec IMPLANT CENTER 2.

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The Device is the same as the Satelec IMPLANT CENTER 2 (K091252, date cleared) Predicate Device in terms of functioning principle. Both devices use the PIEZOTOME Topology. Also the Devices use the same Handpiece and the same range of Dental Bone Surgery Tips.
From internal structure perspective, Devices are very similar because the Switching Power Supply, the Motherboard, the Irrigation Board and the Light Board used are the same for the Device and the Predicate Device.

From external structure perspective, the devices are very similar because the casings are made in self-extinguishing material (UL94-V0) and both Devices are equipped with a large display. Also, both Devices use a multi function footswitch.

Moreover, the materials in contact with the patient are exactly the same.

Discussion of the non-clinical Tests:

The aim of the evaluation was to demonstrate the Substantial Equivalence of the Satelec PIEZOTOME SOLO Device and the selected Predicate Device in terms of Performances. The Performances of the New Device have been evaluated on test bench.
The evaluated Performances were:

- The current values provided in the Piezoelectric Handpiece for each mode.
- The modulation frequencies provided in the Piezoelectric Handpiece for each mode.
- The minimum and maximum irrigation flows available for each mode.
- The leakage currents.

After tests, the obtained results have been directly compared to the Predicate Device Performances. The results of the comparison show that the Performances of the New Device and the Predicate Device are similar.

8 - Conclusion

The Satelec PIEZOTOME SOLO (or the PIEZOTOME SOLO LED available in option) is exactly the same as the identified Predicate Device in terms of Indication For Use..
Because of the used technologies, characteristics and performances are similar to the Predicate Device, the characteristics of the Satelec PIEZOTOME SOLO (or the PIEZOTOME SOLO LED available in option) do not affect the Safety of the patients or of the operator. Moreover, the Effectiveness is the same as of the Predicate Device.

There is no doubt that the Satelec PIEZOTOME SOLO (or the PIEZOTOME SOLO LED available in option) is efficient and safe for the intended uses.
The PIEZOTOME SOLO device is substantially equivalent to the IMPLANT CENTER 2 Predicate Device (K091252, cleared July 22, 2009).

End of Section

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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FEB - 3 2012

Re: K112188
Trade/Device Name: PIEZOTOME SOLO
PIEZOTOME SOLO LED (in option)
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZI
Dated: January 27, 2012
Received: January 30, 2012

Dear Mr. Rosati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 04 – Indication for Use

Indications for Use

510(k) Number (if known): K112188

Device Name: PIEZOTOME SOLO
PIEZOTOME SOLO LED (in option)

Indications for Use:

The intended use of the Satelec PIEZOTOME SOLO (or PIEZOTOME SOLO LED available in option) is to supply utilities to and serve as a base for dental tools and accessories for use by qualified dental practitioners.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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